Lessons learned from the long-term follow-up of a first-generation aortic stent graft

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Objective: **Endovascular repair (EVR) of abdominal aortic aneurysm (AAA) is being performed with increasing frequency worldwide. No studies have a complete follow-up of more than 4 years. Our study objective was to assess the long-term results and the durability of a first-generation stent graft with complete 7-year follow-up.**

Methods: **Between March 1994 and May 1995, 23 consecutive patients underwent treatment with the Chuter stent graft at a single center. All patients underwent computed tomographic scan before discharge, at 3 and 6 months, and annually thereafter. The data were prospectively collected on all patients. The median follow-up period was 72.5 months (range, 0.2 to 91 months). None of the patients were lost to follow-up.**

Results: **Among these 21 men and two women with a median age of 69 years (range, 52 to 85 years), 11 (47.8%) were at high risk. The 30-day technical success rate was 87%. Acute (30-day) complications were one graft deployment failure (4.3%) that necessitated an immediate conversion, 20 intraoperative graft limb kinks (87%), all of which needed additional Wallstent (Schneider, Minneapolis, Minn) placement, four renal failures (17.4%), one type Ia endoleak complicated with AAA rupture (4.3%), and three perioperative deaths (13%). Late complications were eight type I or II endoleaks (34.8%) after a mean delay of 23.9 months (range, 3 to 69 months), 13 proximal stent migrations (56.5%) after a mean delay of 29.6 months (range, 7 to 58 months), six graft limb thromboses (26.1%) after a mean delay of 38.7 months (range, 3 to 71 months), one AAA rupture (4.3%), and 11 deaths (47.8%), with five AAA-related deaths (21.7%). The 3-year, 5-year, and 7-year cumulative endoleak rates were 34%, 41%, and 49%, respectively; the cumulative migration rates were 66%, 75%, and 75%, respectively; and the cumulative open surgery rates were 30%, 50%, and 50%, respectively. At the same intervals, the cumulative survival rates for any death were 69%, 56%, and 49%, respectively; the cumulative survival rates for AAA-related deaths were 82%, 82%, and 73%, respectively; and the cumulative secondary success rates were 54%, 28%, and 28%, respectively.**

Conclusion: **This studies emphasizes the need for close lifelong surveillance of AAAs treated with EVR. Despite the small population of this series, a long-term follow-up highlights that the first-generation homemade stent graft evaluated in this study failed to adequately protect the patient from AAA-related death and that most of the serious complications were related to a late failure of the aortic neck attachment. Better proximal fixation of the aortic stent graft is essential to improve the durability of EVR. (J Vasc Surg 2003;37:367-73.)**

The technical feasibility of endovascular repair (EVR) of infrarenal abdominal aortic aneurysm (AAA) has now been established over the past 12 years. Because the primary objective of treatment is to prevent the patient from any AAA-related death, the crucial issue with respect to EVR is its effectiveness in the long term. Many excellent reports have a comparatively short period of follow-up and provide quite good short-term results.[1-6] Several authors recently reported their mid-term results and reached differing conclusions, with either encouraging findings[7-10] or increasing occurrence of late failure.[11-14] None of these reports have a complete follow-up of more than 4 years. The aim of this study was to provide a long-term perspective on the durability of a first-generation aortic stent graft with complete 7-year follow-up.

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Competition of interest: nil.

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Published online Dec 19, 2002.

0741-5214/2003/$30.00 + 0

doi:10.1067/mva.2003.75

METHODS

Between March 1994 and May 1995, 23 consecutive patients underwent primary EVR of infrarenal AAAs with the Chuter stent graft. This study was approved by the local ethics committee. Written informed consent was obtained from each patient. The data were prospectively collected on all patients until November 2001. None were lost to follow-up. The median follow-up period was 72.5 months (range, 0.2 to 91 months).

Patients were considered at high risk for intervention if they had American Society of Anesthesiologists grade III or IV disease or ruptured AAA. All patients underwent thin-cut (5-mm or less) abdominal and pelvic spiral computed tomographic (CT) scan with contrast enhancement and preoperative angiography before EVR. The eligibility criteria were: AAA of more than 5 cm in diameter or symptomatic and inflammatory or ruptured AAA without serious systemic infection. Patients were excluded on anatomic grounds if: 1, the proximal neck diameter was more than 26

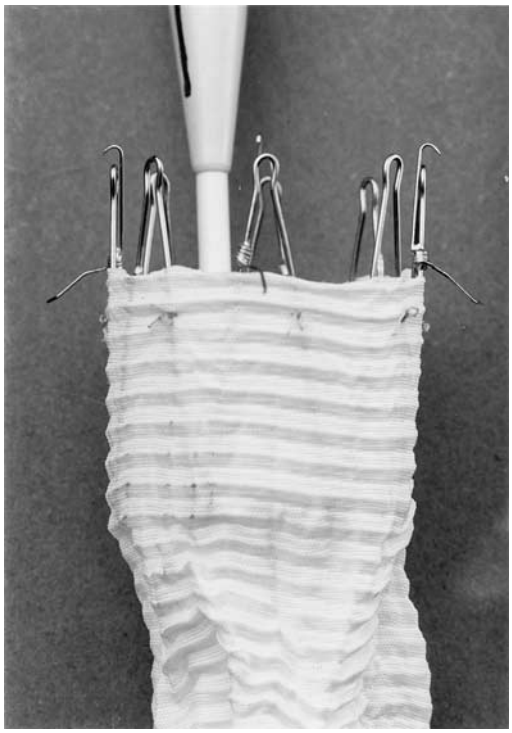

Fig 1. Chuter stent graft with proximal Gianturco Z stent.

mm and the length was less than 15 mm; 2, the proximal neck diameter change from proximal to distal was more than 5 mm (conical neck); 3, the proximal neck angulation was more than 75 degrees; 4, the common iliac artery implantation site diameter was more than 15 mm and the length was less than 20 mm; 5, the external iliac artery diameter was less than 6 mm; and 6, the intestinal perfusion depended on prograde flow through the inferior mesenteric artery (IMA), such as the presence of a large IMA, extensive collateralization between the IMA and the superior mesenteric artery (SMA), flow from the IMA to the SMA, or stenosis of the celiac and SMA. In most cases, the stent graft was oversized 2 to 4 mm larger than the aortic implantation site and 1 to 2 mm larger than the iliac implantation sites. None of the patients had preoperative IMA or lumbar artery embolization to prevent postoperative endoleaks.

The Chuter stent graft existed in straight aortoaortic, tapered aortouniiliac, and bifurcated aortobiiliac configurations. It consisted of a tubular, tapered, or unibody bifurcated conventional graft material (Cooley Verisoft, Meadox Medicals, Inc, Oakland, NJ) and two (for straight grafts) or three (for bifurcated grafts) Gianturco Z stents (Cook, Critical Care, Inc, Ellettsville, Ind) that attached the ends of the graft to the arterial wall. The proximal stent carried four caudally directed barbs and four hooks (Fig 1). All the graft limbs measured 8 mm in diameter with small bell bottoms to prevent leakage. The distal stents were unbarbed. The stent graft was custom made for each patient, on the basis of the findings of preoperative imaging. The concept of the bifurcated device was to deliver the entire bifurcated stent graft and manipulate the contralateral limb into position with catheters, wires, and pull sutures.

All procedures were performed with general anesthesia in the operating room by a team consisting of a vascular surgeon, a radiologist, and two assistants, with a mobile C-arm (Siemens, Siremobil 2000, Erlangen, Germany). Bilateral common femoral arteriotomies were used, except for tubular stent grafts that required unilateral arteriotomy. The technique of Chuter stent graft placement has been previously described.[4,5,15] Postimplantation angiography was performed to assess graft positioning, patency, kinking, and endoleaks. Wallstents (Schneider, Minneapolis, Minn) were routinely placed within the unsupported limbs of the graft where completion angiography showed kinking or stenosis. Endoleaks were treated during the operation with additional endovascular or open measures.

All patients underwent clinical examination and CT scan before discharge, at 3 months and 6 months, and annually thereafter. All the CT scans were analyzed by a radiologist. Perioperative mortality was defined as death within 30 days of operation. The endoleaks were classified according to the White-May[16,17] and Harris[18] definitions: type Ia endoleak from proximal fixation site, type Ib from distal fixation site, type IIa from IMA, type IIb from lumbar artery, type III from defects in the stent graft, and type IV from transient porosity of the graft. Migration was considered significant when the proximal stent had slipped distally 5 mm or more. The occurrence of renal failure was defined as an increase in plasma creatinine level of more than 20% from preoperative value during the same hospital admission. During the follow-up period, a variation in maximal AAA diameter was considered significant at 5 mm or more between two CT scans more than 3 months apart. The technical success, clinical success, continuing success, and secondary success were expressed as defined by the Ad Hoc Committee for Standardized Reporting Practices in Vascular Surgery of The Society for Vascular Surgery/International Society for Cardiovascular Surgery.[19] Data were expressed as mean ± standard deviation. The Kaplan-Meier method was used to examine the cumulative migration and endoleak rates and the cumulative freedom from open surgery and secondary success rates. Life-table survival analysis was determined for all causes of death and for AAA-related deaths. The AAA-related deaths included perioperative deaths, deaths related to secondary procedures, open conversions, and AAA ruptures.

RESULTS

This single center experience of EVR with Chuter stent graft was carried out on 21 men and two women with a median age of 69 years (range, 52 to 85 years). Eleven procedures (47.8%) were conducted in patients at high risk; two of these patients (8.7%) had emergency ruptures. The AAA preoperative sizing is reported in Table I. Fourteen

Table I. Characteristics of patients who underwent EVR

Characteristics	
Elective AAA	21 (91.3%)
Ruptured AAA	2 (8.7%)
Patients at high risk	11 (47.8%)
ASA grade	
I	4 (17.4%)
II	10 (43.5%)
III	7 (30.4%)
IV	2 (8.7%)
Risk factors	
CABG	4 (17.4%)
IHD	9 (39.1%)
Hypertension	9 (39.1%)
POAD	1 (4.3%)
COAD	1 (4.3%)
Renal failure	2 (8.7%)
AAA preoperative sizing* (mm)	
AAA diameter	61.9 ± 11.2
Aortic neck length	31.4 ± 12
Aortic neck diameter	22.4 ± 1.8
RA-Bif length	127.8 ± 18.2
RCI length	56.5 ± 10
LCI length	53 ± 9.5
RCI diameter	13.9 ± 2.7
LCI diameter	12.7 ± 2.8
Device	
Bifurcation	14 (60.9%)
Aortouniiliac	8 (34.8%)
Aortoaortic	1 (4.3%)

*Mean value ± standard deviation.
CABG, Coronary artery bypass graft; *IHD,* ischemic heart disease; *POAD,* peripheral occlusive arterial disease; *COAD,* chronic obstructive airways disease; *RA-Bif,* renal arteries–aortic bifurcation; *RCI,* right common iliac; *LCI,* left common iliac.

Table II. Complications detected during long-term follow-up

Complications	
Acute (30-day) complications and operative outcome	
Graft deployment failure	1 (4.3%)
Immediate conversion	1 (4.3%)
Intraoperative Wallstent placement	20 (87%)
Occluded internal iliac artery	0
Occluded renal artery	0
Endoleak (type Ia)	1 (4.3%)
Renal failure	4 (17.4%)
AAA rupture	1 (4.3%)
Secondary procedure	1 (4.3%)
Perioperative (30-day) mortality	3 (13%)
Duration* (min)	195.4 ± 88.3
Blood loss* (mL)	914.5 ± 1373.4
ICU stay* (d)	1.1 ± 1.8
Hospital stay* (d)	11.1 ± 4.4
Late complications	
Endoleak	8 (34.8%)
Type Ia/b	5 (21.7%)/1 (4.3%)
Type IIa/b	1 (4.3%)/2 (8.7%)
Migration	13 (56.5%)
Delay* (mo)	29.6 ± 12.1
Length* (mm)	36.3 ± 21.4
Thrombosis	6 (26.1%)
Delay* (mo)	38.7 ± 23.2
Ischemic complication	2 (8.7%)
Septic complication	0
Renal failure	0
AAA rupture	1 (4.3%)
Secondary procedure	11 (47.8%)
Overall mortality	11 (47.8%)
Related death	5 (21.7%)
Unrelated death	6 (26.1%)

Endoleak type Ia, proximal fixation site; Ib, distal fixation site; IIa, IMA; IIb, lumbar artery.
*Mean value ± standard deviation.
ICU, Intensive care unit.

Table III. Variation of maximal AAA diameter after EVR according to presence of endoleak or migration

	Enlarging AAA	*Stable AAA*	*Shrinking AAA*
Endoleak, migration	4 (20%)	0	1 (5%)
Endoleak, no migration	3 (15%)	0	0
Migration, no endoleak	0	3 (15%)	5 (25%)
No migration, no endoleak	1 (5%)	1 (5%)	2 (10%)
	8 (40%)	4 (20%)	8 (40%)

bifurcated (60.9%), eight aortouniiliac (34.8%), and one aortoaortic (4.3%) stent grafts were used.

Twenty-two patients (95.6%) had complications related to the EVR during this median follow-up period of 72.5 months (Table II). One graft deployment failure (4.3%) necessitated an immediate conversion (first case). Intraoperative graft limb kinks occurred in 20 patients (87%), all of which were treated with additional Wallstent placement. No intraoperative death occurred. Three patients (13%) died within 30 days of the operation, two of whom were at high risk: one multisystem organ failure at day 17 in the patient with immediate conversion, one rupture at day 6 related to a primary type Ia endoleak and despite a conversion for periaortic ligature placement, and one renal failure at day 14 after successful EVR of a ruptured AAA. Four patients (17.4%) had perioperative renal failure. Three of the patients died within 30 days of operation, and one had spontaneously regression. The 30-day technical success rate was 87%.

Secondary endoleaks were observed in eight patients (34.8%) with a mean delay of 23.9 months (range, 3 to 69 months). One case of type Ib endoleak (4.3%) occurred with the single aortoaortic device. No type III or type IV endoleaks were observed. Thirteen patients (56.5%) had proximal stent migrations that occurred after a mean delay of 29.6 months (range, 7 to 58 months). Stent graft migrations led to secondary type Ia endoleaks in four patients and to graft limb occlusions in three patients. Table III describes the impact of endoleak and migration on variation in maximal AAA diameter (the three perioperative deaths have been excluded). Kaplan-Meier cumulative endoleak, migration, and open surgery curves are shown in Fig 2. The 3-year, 5-year, and 7-year cumulative endoleak rates were 34%, 41%, and 49%, respectively; the cumulative

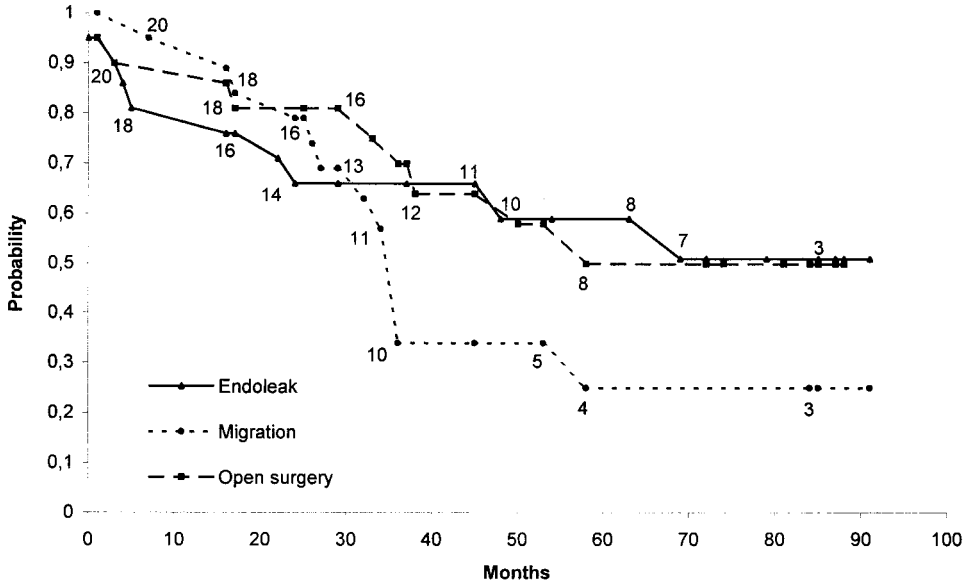

Fig 2. Life-table analysis of freedom from endoleak, migration, and open surgery.

Table IV. Management of Chuter stent graft failures

	n	*Endoleak*	*Migration*	*Thrombosis*
Open repair	9	4	7	3
Delay* (mo)		25.5 ± 19	35.4 ± 14.4	26 ± 23.3
Endovascular repair	3	3	0	0
Delay* (mo)		34.3 ± 22.5	–	–
Conservative management	7	2	6	3

*Mean value ± standard deviation.

migration rates were 66%, 75%, and 75%, respectively; and the cumulative open surgery rates were 30%, 50%, and 50%, respectively. Six patients (26.1%) had graft limb thromboses that occurred after a mean delay of 38.7 months (range, 3 to 71 months). Only two of these patients (8.7%) were symptomatic with lower limb ischemia: one was nonprogressive and the other needed a femorofemoral bypass. The 3-year, 5-year, and 7-year cumulative clinical success rates were 47%, 24%, and 24%, respectively, and the cumulative continuing success rates were 28%, 6%, and 6%, respectively.

Secondary procedures were undertaken in 12 patients (52.2%) with a mean delay of 29.5 months (range 0.2-66 months) as shown in Table IV. Open repair was performed in nine patients (39.1%) with type Ia endoleaks, migrations, or graft limb thromboses. These included open suture of the stent graft top end (n = 5), stent graft explantation and open aneurysm repair (n = 2), periaortic ligature placement (n = 1), and femorofemoral bypass (n = 1). Two of these patients died in the postoperative period, and the remaining seven patients had effective repairs. EVR was undertaken in three patients (13%) with type Ib or type II endoleaks. These included embolization (n = 2) and additional stent graft placement (n = 1). During the follow-up period, all of these patients had an enlarging AAA related to persistant endoleak, but no rupture occurred. Conservative management was adopted in seven patients (30.4%). Five of these patients had a shrinking AAA, and one had a stable AAA, whereas one patient with an enlarging AAA related to type IIb endoleak and migration died from late rupture.

The overall mortality concerned 11 patients (47.8%). Six patients (26.1%) died of causes unrelated to the AAA (three were at high risk): cancers (n = 3 patients at 37, 45, and 54 months), liver failure (n = 1 patient at 25 months), myocardial infarction (n = 1 patient at 29 months), and acute cholangitis (n = 1 patient at 42 months). Five patients (21.7%) died of AAA-related causes (three at high risk): perioperative deaths (n = 3 patients), hemorrhagic complications after secondary open repair (n = 1 patient at 17 months), and late AAA rupture (n = 1 patient at 74 months). Kaplan-Meier cumulative survival and secondary success curves are shown in Fig 3. The 3-year, 5-year, and 7-year cumulative survival rates were 69%, 56%, and 49%, respectively, for any death and were 82%, 82%, and 73%, respectively, for AAA-related death. At the same intervals, the cumulative secondary success rates were 54%, 28%, and 28%, respectively.

DISCUSSION

The advent of endovascular techniques has permitted the management of aortic aneuryms with a less aggressive approach, avoiding laparotomy and aortic cross clamping. During this period, significant advances have been made. At the beginning, in most of the series, stent grafts were reserved for patients who were considered at high risk for standard open repair. When the perioperative safety of the

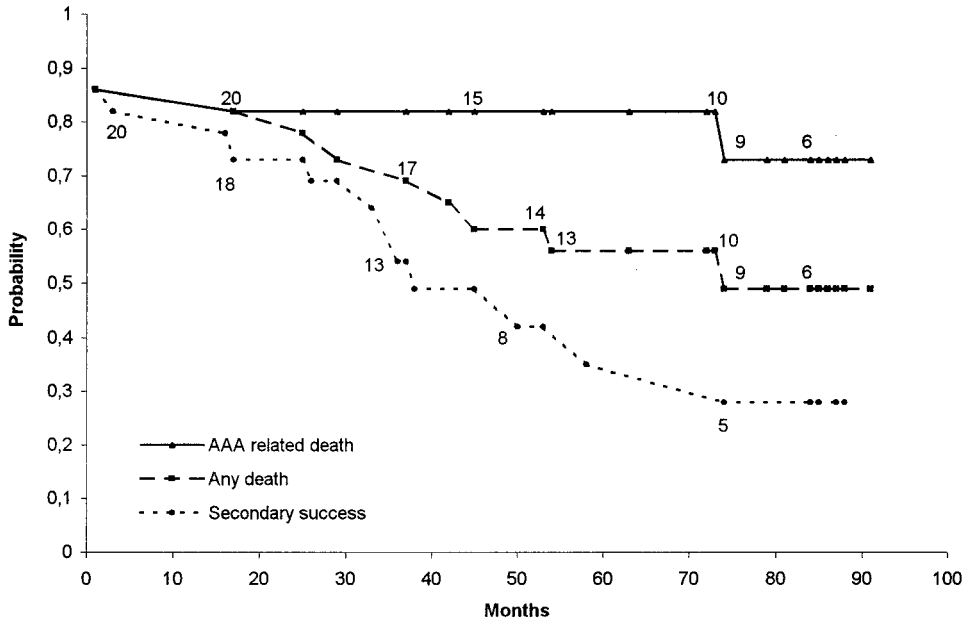

Fig 3. Life-table analysis of survival and secondary success.

procedures improved and good short-term outcome was shown, stent grafts were used to treat others.[3] In advocating EVR for these patients, a critical analysis of late outcome is necessary.

Even though a relatively large number of endovascular procedures have been analyzed, most patients in these study populations had a follow-up period of less than 2 years. Some earlier studies of mid-term results after EVR of AAA have been reported with mixed conclusions. Ohki et al[11] performed 239 EVRs for nonruptured AAAs, 86% in patients at high risk. During follow-up to 75 months (but mean, 15.7 months), complications occurred with increasing frequency and the overall life-table patient survival rate at 5 years was 37%. May et al[9] compared two generations of stent grafts and showed that survival and probability of graft failure were significantly higher with first-generation stent grafts than with second-generation stent grafts during a follow-up period of 48 months. Sultan et al[8] reported 36 EVRs with a mean follow-up period of 29 months. Their technical, clinical, continuous, and secondary success rates were 78%, 91%, 89%, and 91%, respectively. Zarins et al[7] reviewed 1192 patients treated with the AneuRx stent graft and reported a rupture-free rate of 99.5% at 3 years and an overall survival rate of 86% at 3 years.

None of the patients in this series were lost to follow-up (median duration, 72.5 months). The overall mortality rate was 48%, and the 7-year cumulative survival rate was 49% for any death and 73% for AAA-related deaths. The incidence rate of complications was higher than that of most other series. First-generation devices and the learning curve probably contributed to a relatively high complication rate. Above all, the duration of follow-up has permitted detection of late complications, which are not encountered during the first 2 or 3 years. Prinssen et al[13] explained that failure of the proximal attachment system related to aortic enlargement may not become apparent before 3 or 4 years of follow-up have elapsed. Hölzenbein et al[20] reported that 26% of their 173 patients needed a secondary procedure during mid-term follow-up because complications appeared even after periods of more than 2 years.

Migration represents one of the main problems encountered with the Chuter stent graft. This occurred at a mean delay of 30 months, despite the presence of hooks and barbs on the proximal stent. However, several explants showed the hooks and barbs were trapped in the cloth and not in the aorta as a result of "muzzle" loading.[5,21,22] Two stent graft explantations were reported in this series. In these two cases, the structural integrity of the conventional graft material was respected and the examination of the Gianturco Z stents showed no stent, hooks, or barb fracture. As shown on the Kaplan-Meier life-table analysis, the 7-year cumulative migration rate was 75%. Stent graft migrations have already been described with the Chuter and the Ivancev-Malmö devices[23] as a consequence of limited oversizing, ineffective barbs, and high distal force related to the change in diameter between aortic and iliac segments, which greatly increased the incident energy and force of flowing blood. Harris et al[24] showed that migration is an important cause of proximal fixation site endoleak and is significantly associated with rupture. Factors contributing to migration of stent grafts have been emphasized by the Malmö group[22]: inadequate fixation mechanism and improper device placement in the perirenal aorta and adverse proximal neck morphology (wide, >30 mm; short, <10

mm; conical, calcified and thrombus-lined necks). Several strategies have been used to avoid migration, including more hooks, higher radial force, and suprarenal attachment of the proximal stent. These lessons are reflected in more recent device designs, such as the Zenith stent graft.[2,6] Moreover, it has been shown that in some cases there is a continuous aortic enlargement of approximately 1 mm/y at the level of the proximal endovascular anastomosis.[13] With the current practice of oversizing the stent graft to the proximal neck,[25] a loss of the endovascular seal may not become manifest until 3 or 4 years after EVR of AAA is performed. If the potential for migration continues for the life of the patient, the lack of durability is a concern, especially for patients at good risk. An effective way to prevent subsequent migration of stent graft would be to attach the prosthetic graft to the aortic neck with a system of endovascular staples or sutures. As recently proposed by Trout and Tanner,[26] we are developing a prototype of nitinol endovascular staple to provide a more secure proximal anastomosis of the stent graft.

The 39.1% incidence rate of endoleak that was found in this series is inside the reported range, which varies from 10% to 44%.[1-3,12,19,27-29] Most of the type Ia endoleaks were caused by migration. One patient died at day 6 after surgery of rupture related to a primary type Ia endoleak. This emphasizes that type I endoleak is an important risk factor for postoperative rupture and justifies immediate intervention (open or endovascular). Another patient died at 74 months after surgery of late rupture related to a type IIb endoleak and migration. Type II endoleaks may also result in aneurysm rupture.[30] Persistent sac pressure or endotension causes it to expand and rupture.[31] The Eurostar experience[24] has shown that, even if direct measurement of endotension is not yet possible, continued expansion or reexpansion of the sac after surgery is a strong indication of its presence and, therefore, a strong indication for secondary intervention. In this series, the increase in AAA diameter seemed to be more directly related to endoleak than to migration. Nearly all cases of endoleak with or without migration were associated with an increasing size in maximal AAA diameter, whereas all cases of migration without endoleak had stable or shrinking AAA probably because there were small migrations not yet resulting in leaks.

The late graft limb thromboses that occurred in this series are probably related to the use of an unsupported stent graft. Intraoperative Wallstent placement was used where kinking or stenosis was seen on completion angiography. This was a frequent (87%) finding. Fully supported stent grafts have been found to provide improved patency compared with unsupported stent grafts.[32] Unibody unsupported devices have advantages in avoiding the separation of modular graft limb components that may occur as the AAA morphology changes and lead to type III endoleak. Two complications notable by their absence are embolism and colon ischemia. The policy of systemic heparinization and preserving internal iliac artery flow, if at all possible, is partly attributable to concern for colonic perfusion because EVR affords no opportunity for IMA reimplantation.

The need for secondary procedures is an important indicator of long-term success of EVR. Many of the recent publications involve a relative limited follow-up. In the Eurostar registry, a population of patients that had at least 1 year of follow-up was studied. Overall, 18% of these had a secondary procedure, occurring after a mean delay of 14 months, and the rate of freedom from intervention at 4 years was 62%.[14] In our series, 54.5% of patients had a secondary procedure and the 3-year, 5-year, and 7-year cumulative open surgery rates were 30%, 50%, and 50%, respectively, reflecting the high rate of late complications. Most of the secondary procedures occurred from the third year of follow-up and were open repairs. At the beginning of our experience, we had no appropriate device to treat with an endovascular method a proximal migration of unsupported stent graft; we preferred to realize an aortic cross clamping and a direct suture between the aorta and the top of the stent graft. The high incidence rate of late secondary procedure emphasizes the need for lifelong surveillance. In most of the series,[33-36] the 5-year cumulative survival rate in patients who underwent operation for AAA (except ruptured AAA) ranged from 63% to 83%; a population with same age and gender had a 5-year survival rate of 80% to 85%. As expected in a population with nearly 50% patients at high risk, the 5-year cumulative survival rate was 56% for any death and 82% for AAA-related deaths.

CONCLUSION

EVR of AAA has been proven to be technically feasible. Stent grafts can fail in a greater number of ways and with greater frequency than standard AAA grafts placed during an open operation.[12,36] It is necessary to keep patients informed that maintenance procedures may be necessary. The stent graft was deployed successfully in most cases with effective aneurysm exclusion. The late complications included type Ia endoleak, stent graft migration, and graft limb thrombosis. Although the latter problem has been surmounted by fully supported limbs, the other two remain a challenge to the durability of EVR, even if migration should not occur with such a high incidence with the new-generation stent grafts. All patients managed with a first-generation aortic stent graft and with stable or enlarging AAA related to endoleak or migration should have an open or EVR to avoid any AAA rupture. Despite the small population of this series, a long-term follow-up underlines that the first-generation homemade stent graft evaluated in this study failed to adequately protect the patient from AAA-related death and that most of the serious complications were related to a late failure of the aortic neck attachment. This state of affairs may change as better devices with improved proximal fixation or new systems of endovascular suture become available to prevent leaks and slips.

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Submitted Mar 28, 2002; accepted Jul 24, 2002.